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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/423,516	02/10/2000	ERMANNO GHERARDI	1090-26	6832

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EXAMINER

HAYES, ROBERT CLINTON

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 08/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/423,516

Applicant(s)

GHERARDI ET AL.

Examiner

Robert C. Hayes, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 64-86 is/are pending in the application.
- 4a) Of the above claim(s) 80-86 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 64-79 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 64-86 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/09/04 has been entered.
2. The amendment filed 7/09/04 has been entered.
3. It is again noted that the rejections of claims 31-32 & 34 under 35 U.S.C. 102(a) as being anticipated by Sakata et al and Lokker et al were previously withdrawn due to the cancellation of these claims which, in contrast to Applicants' assertions, supported the basis for the lack of unity made final in Paper No: 17, due to the absence of a "special" technical feature for the invention recited in originally presented claim 31. Again, note that PCT Rule 13 does not provide for multiple products or methods within a single application.

This application contains claims 80-86 drawn to an invention nonelected with traverse in Paper No. 17. A complete reply to the final rejection in Paper No: 17 must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144). See MPEP 821.01.

4. The rejection of claims 64-79 under 35 U.S.C. 112, second paragraph, as being indefinite for reciting position numbers to no known reference sequence is withdrawn due to the amendment of the claims. However, it is noted that the Examiner's suggestion to amend the claims to recite that the wildtype human HGF is of SEQ ID NO: 2, which should have obviated most of the rejections made of record, was ignored by Applicants.
5. Applicant's arguments filed 4/09/04 have already been fully considered in the Advisory action in Paper No: 20040614, but were not deemed to be persuasive.
6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
7. Claims 64-79 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reason made of record in Paper NOs: 18 (mailed 6/27/02) & 24 (mailed 1/09/04), and as follows.

As previously made of record, base claim 64 still recites insufficient structure, and therefore, remains not limited to a variant that merely replaces a positively charged amino acid residue in the hairpin loop structure of wildtype human HGF [which remains not structurally defined]; thereby, still not meeting the written description guidelines for the reasons extensively

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made of record; consistent with that held by the courts in *Fiers v. Revel* and *Univ. California v. Eli Lilly and Co.*, previously made of record. See MPEP 2163.

8. Claims 64-79 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention

No proper basis nor conception in context with that described within the specification exists for reciting the hairpin structure of SEQ ID NO: 3 into any different "wild-type human HGF" molecule, except for the human wild-type HGF molecule of SEQ ID NO: 2; thereby, broadening the scope of that claimed, which therefore, constitutes new matter.

9. Claims 64-79 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to HGF variants that are structurally characterized and claimed, does not reasonably provide enablement for any biologically functional equivalent forms of HGF with no recited structural characteristics. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, for the reason made of record in Paper No: 18 (mailed 6/27/02 & 24 (mailed 1/09/04), and as follows.

As previously made of record, no base structure for what constitutes the wildtype HGF from which the variant HGF molecule is derived is defined in the currently recited claims. Thus, Applicants' arguments remain moot, for the reasons previously made of record; consistent with

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the teachings of Rudinger previously made of record, and that held by the court in *Ex parte Maizel* previously made of record.

Lastly, although Applicants are correct that *In re Schechter* does not apply "so long as support for same is in the specification" for claims 74-77, such claim language still recites insufficient structural characteristics, in order for the skilled artisan to know how to make and use the invention, as currently claimed, for the reason previously made of record. Thus, Applicants' arguments are not persuasive.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (571) 272-0885. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961. The fax phone number for this Group is (703) 872-9306.



Robert C. Hayes, Ph.D.

August 4, 2004

ROBERT C. HAYES, PH.D.
PATENT EXAMINER